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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,521	12/05/2003	Atul Varadhachary	HO-P02703US2	8270
26271 7590 08/14/2009 FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095				
EXAMINER				
KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
08/14/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/728,521

Applicant(s)

VARADHACHARY ET AL.

Examiner

CHIH-MIN KAM

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-10, 14-20, 26-32 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10, 14-20, 26-32 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The finality of previous Office Action dated July 5, 2007 is withdrawn due to a new ground rejection.

Status of the Claims

2. Claims 1, 7-10, 14-20, 26-32 and 38-40 are pending and examined.

In response to Applicants' Appeal Brief filed April 2, 2008, an Examiner's Answer was submitted on June 10, 2008. The Board of Patent Appeals and Interference has made the decision on the Appeal on May 12, 2009, in which the obviousness rejection of claims 1, 7, 14, 17-19, 26-32 and 38-40 was affirmed, and the provisional obviousness-type double patenting rejection was vacated.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 1, 7, 14, 17-19, 26-32 and 38-40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-22, 26-30 and 50-51 of copending application 10/663,258 (now U.S. Patent 7,524,814), is withdrawn in view of Board's decision and the allowable claims in the patent that differ from the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Previous rejection of claims 1, 7, 14, 17-19, 26-32 and 38-40 under 35 U.S.C. 103(a) as being unpatentable over Van Bree *et al.* (WO 01/72322, October 4, 2001) is maintained, and claims 8-10, 15-16 and 20 are further added to the rejection.

Regarding the rejection of claims 1, 7, 14, 17-19, 26-32 and 38-40, please see paragraph 2 at pages 2-3 of the Office Action dated July 5, 2007, and pages 3-4 of the Examiner's Answer dated June 10, 2008.

Van Bree *et al.* teach the lactoferrin composition comprises full-length lactoferrin (LF), fragments of LF, and/or variants of LF (e.g., N-terminal variant) and a pharmaceutically acceptable excipient (page 27, lines 9-24) and the lactoferrin can be naturally occurring LF such as human LF or recombinantly made in transgenic non-human animal such as bovine (page 5, line 29-page 6, line 2; claims 8-10). Van Bree *et al.* also teach an effective dosage is generally between 10 and 100 mg of intact human lactoferrin (hLF Mr. 77,000) per kilogram of body weight, where the dosage can be administered at least daily for a period of a week, a month or a year (page 23, lines 33-page 24, line 29). Thus, the effective amount of hLF would be between 700 mg and 7000 mg (7 g) per day if assuming the weight of average person is 70 kg, and the effective amount of hLF fragment would be between 14 mg and 140 mg per day if assuming the molecular weight of LF fragment is 1500 (page 23, line 33-page 24, line 12; claims 15-16). Although Van Bree *et al.* do not specifically indicate using a nasogastric tube for oral administration, Van Bree *et al.* teach for oral administration, the active ingredient such as LF or LF variant can be administered in solid dosage forms such as capsules, tablets and powders, or in liquid forms such as elixirs, syrups and suspensions, and the compressed tablets can be enteric-coated for selective disintegration in the gastrointestinal tract (page 26, lines 1-21). Thus, at the

time of invention was made, it would have been obvious to one of ordinary skill in the art to orally administer the active ingredient in liquid forms using a nasogastric tube (claim 20) because this method provides an alternative way to administering liquid form of LF composition, which results in the claimed invention and was, as a whole, *prima facie* obvious at the time the claimed invention was made.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

August 12, 2009